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10/580,139

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Leon Rudakov

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EXAMINER

DORNBUSCH, DIANNE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,139	<b>Applicant(s)</b> RUDAKOV ET AL.	
	<b>Examiner</b> DIANNE DORNBUSCH	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-22, 24-36 and 39-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-22, 24-36 and 39-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2009 has been entered.\

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 34, 41, and 72 mention a substantially uniform porosity, but the original disclosure describes a range of pores that can be used on the membrane without mentioning if it is placed uniform or not throughout the membrane. Furthermore, as noted by applicant in the response filed February 26, 2009, in page 14 last paragraph, the porosity in Fig. 10 is uniform porosity. As seen, the original disclosure has support

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for the membrane having a uniform porosity (Fig. 10) or a non-uniform porosity but there is no reference in either the original drawings or specification to the porosity being substantially uniform.

In addition, claims 1, 34, 41, and 72 state that blood flow into the aneurysm is substantially not allowed. This is considered new matter since the original disclosure only states that the blood flow into the aneurysm is prevented (Page 4 Line 12 and Page 15 Lines 24) but it does not state that it is substantially prevented.

4. Claims 1-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 34, 41, and 72 disclose that the membrane is of a uniform porosity which allows blood to flow through the membrane into branch vessels but prevents it from flowing into the aneurysm. It is unclear to the examiner how blood cannot pass through a portion, but can pass through another portion of the membrane if the pores are uniform.

The membrane as claimed and as disclosed in the specification does not have a sufficient description regarding the membrane. The membrane is claimed as having a uniform porosity which if used in a vessel to prevent blood from flowing into the aneurysm it would mean that flow would not pass through the aneurysm nor any other branch vessel that is covered by the membrane. However, there could be other factors

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that affect the membrane which would allow some blood to flow through the branch vessel and not the aneurysm as noted in applicants arguments filed February 26, 2009, in page 15 last paragraph. This factors such as thickness of the membranes and the density of the porous which are not described in the original disclosure, would require undue experimentation in order to get the appropriate value that would allow blood to flow through one portion but not through the other portion. Furthermore, without having any clear disclosure on the factors that affect the uniform porous membrane from allowing flow through one portion but not through the other, it is unclear how one person of skill in the art would make the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 34, 41, and 72 disclose that the pores are uniform, that the blood cannot pass to the aneurysm through the membrane, and that blood can pass through the membrane into branch vessels.

It is unclear to the examiner how blood cannot pass through a portion, but can pass through another portion of the membrane if the pores are uniform.

7. Claims 62 and 65-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention.

Claim 62 is dependent on claim 14 which is a cancelled claim.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-13, 15-20, 24-31, 35, 36, 41-56, 58, 59, 62-69, 73, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Fierens et al. (2002/0035394).

Claims 1 and 41:

Rudakov discloses a medical device (11) for insertion into a bodily vessel, the device comprising: a mechanically expandable device (16) expandable from a first position to a second position (Col. 5 Lines 15-17), such that in the second position, an exterior surface of said mechanically expandable device engages with the inner surface of the vessel so as to maintain a fluid pathway through said vessel (Col. 5 Lines 13-17). The mechanically expandable device (16) is engaging through the vessel by expanding radially and providing the rigidity on the top sleeve (13) in order to maintain contact with the vessel.

Furthermore Rudakov discloses that a porous membrane expandable (12, 13) (Col. 2 Line 16) in response to expansion of the mechanically expandable device (16) (Col. 5 Lines 15-17); wherein at least a portion of the membrane is secured to the

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mechanically expandable (the membrane is attached to the mechanically expandable device by using rings 17 and by everting the membrane in order to hold the mechanical expandable device as disclosed in the Col. 3 Lines 48-65), such that a proximal end of the membrane is proximate to a proximal end of the mechanically expandable device, and a distal end of the membrane is proximate to a distal end of the mechanically expandable device (Col. 3 Lines 48-65); and wherein the membrane has a porosity over a length extending from the distal end of the membrane to the proximal end of the membrane (the membrane is made of a material which contains pores throughout the material in order to optimize desired biological responses; wherein when the mechanically expandable device is expanded in the bodily vessel, adjacent to the aneurysm, the membrane is effective to: obstruct blood flow from the vessel into the aneurysm (the device can be placed in a vessel to treat an aneurysm by placing it between the opening where part of the device is covering the aneurysm thereby obstructing the flow by using the porous membrane); and permit blood flow through pores in the membrane and into branch vessels arising from the bodily vessel.

With respect to the statements of what the membrane is effective to do (capable of), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Additionally, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so

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perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Rudakov teaches all the claimed limitations discussed above however, Rudakov does not disclose that the membrane has a substantially uniform porosity.

Fierens discloses a mechanically expandable device (32) with a membrane (38) that contains a substantially uniform porosity (last sentence of [0024] and [0087]) along its length (Fig. 11 and [0087] last line).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov with a uniform porosity in view of the teachings of Fierens, in order to promote cell in growth as well as reducing the risk of embolic release through out the length of the device equally.

Claims 2, 18, 42, and : Rudakov in view of Fierens discloses the claimed invention except for distance between adjacent pores being between 40 to 100 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the distance between adjacent pores between 40 to 100 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 3 and 43: Rudakov discloses that the membrane (12, 13) is made of a biocompatible and elastomeric polymer (Col. 2 Lines 10-21).

Claims 4 and 44: Rudakov discloses that the membrane (12, 13) has a thickness of about 0.0005 to 0.005" (Col. 2 Lines 22-25).



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Claims 5 and 45:

Rudakov discloses all the claimed limitations discussed above but it is silent in the distance between adjacent pores, therefore it is silent on the material surface area of the membrane being from about 25-75%.

Although Rudakov does disclose the range size for the pores, which indicates that the surface area of the membrane is less than 100%. By identifying the pore size and the spaces between each pore the surface area of the membrane can be identified.

As mentioned in the rejection of claim 2, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the distance between adjacent pores between 40 to 100 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a membrane with a surface area between 25 to 75%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 6 and 46: Rudakov discloses that the membrane (12, 13) has pores between 20 to 100 microns in size (Col. 2 Lines 28-29).

Claims 7 and 47: Rudakov discloses that the membrane (12, 13) is made from polymeric material (Col. 2 Lines 10-13).

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Claims 8 and 48: Rudakov discloses that the polymeric material forms multiple sub-layers mixed with drugs or reagents (Col. 3 Lines 26-29 and Col. 4 Lines 41-43 and Lines 58-61). The layers are formed by each of the coatings on the membrane.

Claims 9 and 49: Rudakov discloses that the membrane (12, 13) is capable of isotropic expansion (Col. 5 Lines 13-17).

Claims 10 and 50: Rudakov discloses that the membrane (13) is disposed on the exterior surface of the device (16) (Col. 2 Lines 4-5 and Fig. 1).

Claims 11 and 51: Rudakov discloses that the membrane (12, 13) completely surrounds the device (Col. 3 Lines 52-58). There is only one material use to form the outer membrane (13) and the inner membrane (12) which surrounds the device (16) as disclosed in the method of manufacturing in Col. 3 Lines 42-67.

Claims 12 and 52: Rudakov discloses that the membrane (12, 13) circumferentially surrounds a portion of the device (Fig. 2 and Col. 3 Lines 48-65).

Claims 13 and 53: Rudakov discloses that the membrane (12, 13) covers a portion of the device (Fig. 2).

Claims 15 and 54: Rudakov discloses a membrane is made from a solid polymer (Col. 2 Lines 10-13). The polymer is solid since it has three dimensions (length, breadth, and thickness) (Col. 2 Lines 22-25 and Fig. 1-4).

Claims 16, 17, 55, and 56:

Rudakov discloses each and every structural element of the membrane set forth in claims 16 and 17 (Col. 2 Lines 28-29).

Rudakov teaches that the membrane comprises pores between 20 to 100 microns in size (Col. 2 Lines 28-29), but is silent as to the method of making the pores. The claimed phrase “fabricated pores” and “fabricated by laser drilling” are being treated as a product by process limitation; that is, that the pores are made by laser drilling.

Fierens teaches that the membrane has fabricated pores ([0024]) and that the pores are fabricated by laser drilling ([0024]).

Therefore, even if “laser drilling” results in different structural characteristics of the end product than other pore fabricating methods, it still would have been *prima facie* obvious at the time the invention was made to use a “laser drilling fabrication method” in Rudakov as claimed since Fierens teaches that laser drilling is recognized as a useful technique for forming the pores in the membrane.

Claims 19 and 58: Rudakov discloses that the membrane (12, 13) comprises a plurality of polymeric strips (17) (Col. 2 Lines 55-58) secured to the mechanically expandable device (16) (Col. 2 Lines 5-6 and 63-64).

Claims 20 and 59: Rudakov in view of Fierens discloses the claimed invention except for the strips being less than 0.075 mm and a distance between adjacent strips being less than 100  $\mu\text{m}$ . It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the size of the strips less than 0.075 mm and a distance between adjacent strips less than 100  $\mu\text{m}$ , since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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Claims 24 and 62: Rudakov discloses that the mechanically expandable device (16) comprises a generally tubular structure (Fig. 1) having an exterior surface defined by a plurality of interconnected struts (26 with 22 and 23) having interstitial spaces therebetween (Fig. 1).

Claims 25 and 63: Rudakov discloses the mechanically expandable (16) device is balloon expandable (Col. 5 Lines 13-17).

Claims 26 and 64: Rudakov discloses that the mechanically expandable device (16) is a stent (Fig. 1). Figure 1 shows that the expandable device (16) has the structure of a stent as well as Rudakov discloses that the final product is a stent-graft where the expandable device (16) is the stent and the graft is the membrane (12, 13).

Claims 27 and 65: Rudakov discloses that the membrane (12, 13) is supported by the generally tubular structure (Fig. 1) and is attached to at least one strut (26) as seen in Fig. 1-3 as well as in the explanation of the manufacturing process (Col. 4 Lines 1-14) where the membrane (12, 13) are placed on the expandable device (16).

Claims 28 and 66: That the membrane (12, 13) is tubular (Fig. 1-2) and wherein the membrane (30) is disposed onto the outer surface of the stent (Fig. 1-2).

Claims 29 and 67: That the membrane (12, 13) is a segment of a tubular structure (Fig. 1-2) disposed onto a portion of the outer surface of the stent (Fig. 1-2).

Claims 30 and 68: Rudakov discloses that the at least one drug or reagent is in any one form selected from the group consisting of: solid tablet, liquid and powder (Col. 4 Lines 36-49).

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Claims 31 and 69: Rudakov discloses that at least one radiopaque marker is provided on the mechanically expandable device (16) to improve visibility of the device during and after insertion (Col. 4 Lines 17-21).

Claims 35, 36, 73, and 74: Rudakov discloses a method of manufacturing comprising: disposing the generally tubular structure on a mandrel (51); and disposing the membrane (12,13) onto the outer surface of the mechanically expandable device (16). The device has two membranes, where the first membrane (12) is first disposed on the mandrel (51) and then the expandable device/stent (16) is placed on the mandrel as well as the connecting rings (17). After this part the membrane (13) is placed on top of the mechanically expandable device/stent as it is disclosed in Fig. 3-4 and Col. 4 Lines 1-14.

10. Claims 2, 5, 18, 20-22, 42, 45, 57, and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Fierens et al. (2002/0035394) and further in view of Solovay (5,769,884) .

Solovay discloses a medical device (10) for insertion into a bodily vessel, the device comprising: a mechanically expandable device (20) expandable from a first position to a second position (Col. 3 Line 44), said mechanically expandable device (20) is expanded radially outwardly to the second position such that the exterior surface of said mechanically expandable device engages with the inner surface of the vessel (16) so as to maintain a fluid pathway through said vessel (Col. 3 Lines 50-59). Figure 4 shows how the expandable device (20) is in contact with the vessel (16).

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Furthermore it is disclosed that a membrane expandable (30) from a first position to a second position in response to expansion of said mechanically expandable device (20) (Fig. 3-4 where the device is expanded), said membrane (30) being positioned proximal to the aneurysm (15) and obstructing blood circulation to the aneurysm (15) when expanded to the second position (Fig. 3-4), and at least a portion of the membrane (30) is secured to the mechanically expandable device (20) to maintain the position of the membrane (30) relative to the mechanically expandable device (20) when expanded to the second position (Col. 3 Lines 45-50); wherein the membrane (30) is permeable (it can be penetrated, especially by liquids or gases, depending on the size of the pores, such as drug agents) and porous (Col. 3 Line 45-46), the size of the pores of the membrane and the ratio of the material surface area of the membrane being such that blood supply to perforators and/or microscopic branches of main brain arteries is permitted to improve healing of the bodily vessel but blood supply to the aneurysm is prevented (Col. 2 Lines 1-9).

Claims 2, 18, 42, and 57:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that the distance between adjacent pores is from 40 to 100 microns.

Solovay discloses that the distance between adjacent pores is from about 40 to 100 microns (Col. 2 Lines 51-55 and Col. 5 Lines 51-53). The pore size is between 30-120 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7) therefore the space between the

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pores is in the specified range. For example if the pore size is 30 microns than the space between the pores can be 90 microns.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with the specified distance range between adjacent pores in view of the teachings of Solovay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 5 and 45:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that the surface area of the membrane is from 25 to 75%.

Solovay discloses that the ratio of the material surface area of the membrane (30) is from about 25 to 75%. Do to the size of the pores and the space between the pores the surface area of the membrane is between that range. For example if the membrane has pores spaced close together like the one shown in Fig. 6 section 12 it can be seen that if the pore size were 30 microns and the space between them were 15 microns the surface area would be around 30%-50%.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with the specified surface area range of the membrane in view of the teachings of Solovay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

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the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 20 and 59:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that the strips are less than 0.075 mm and a distance between adjacent strips is less than 100  $\mu$ m.

Solovay discloses that the membrane (30) comprises a plurality of polymeric strips (the fiber disclosed in Col. 7 Lines 15-16) secured to the mechanically expandable device (20) (Col. 7 Lines 45-48). Additionally, Solovay discloses that the strips (the fiber) are less than 0.075 mm (Col. 7 Lines 15-18) and the distance between adjacent strips (fibers) is less than 100 microns. There are strips that are grouped together which will have a distance of less than 100 microns, furthermore the strips are interlaced forming the pores which are around 30-120 microns. So the distance from one strip is less than 100 microns.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with the specified distance range between adjacent strips and the size of the strips in view of the teachings of Solovay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 21, 22, 60, and 61:



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Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that the membrane comprises a mesh.

Solovay discloses that the membrane comprises a mesh secured to the mechanically expandable device (20). The mesh is the membrane (30) which is braided which forms a mesh structure (Col. 3 Lines 45-48).

Additionally Solovay discloses that the spaces (the pores) of the mesh (30) are less than 100 microns (Col. 2 Lines 34-35 and Col. 5 Lines 5-7).

However, Solovay discloses the claimed invention except that the width of the meshing is between 0.025 to 0.050 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width of the meshing be between 0.025 to 0.050 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with a mesh membrane in view of the teachings of Solovay, in order to fabricate the pores by spacing the area between each wire in the mesh to the desired pore size.

11. Claims 34, 39, 40, 72, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume et al. (5,948,018) in view of Fierens et al. (2002/0035394).

Claims 34 and 72:

Dereume discloses a medical device for treating a bifurcation or trifurcation intracranial aneurysm between at least two bodily vessels, the device comprising: a first mechanically expandable device (57), expandable from a first position to a second position (Fig. 9-13), such that, in the second position, an exterior surface of the first mechanically expandable device engages with an inner surface of a first branch vessel arising from a parent vessel so as to maintain a fluid pathway through the first branch vessel (Fig. 13); a second mechanically expandable device (55, 56), expandable from a first position to a second position (Fig. 9-13), such that, in the second position, an exterior surface of the second mechanically expandable device engages with an inner surface of a second branch vessel arising from the parent vessel so as to maintain a fluid pathway through the second branch vessel (Fig. 13). The mechanically expandable devices are engaging through the vessel by expanding radially and providing the rigidity on the top membrane in order to maintain contact with the vessel.

Furthermore Dereume discloses a porous membrane (53, 54) (Claim 1 and 18) , and at least a portion of a proximate end of the membrane is secured to the first mechanically expandable device and a distal end of the membrane is secured to the second mechanically expandable device (Fig. 10); the membrane has a porosity over a length extending from a distal end of the membrane to a proximal end of the membrane (Fig. 10); and wherein, when the first mechanically expandable device is expanded in the first branch vessel adjacent to the aneurysm and the second mechanically expandable device is expanded in the second branch vessel adjacent to the aneurysm position (the device can be placed in a vessel to treat an aneurysm by placing it

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between the opening where part of the device is covering the aneurysm thereby obstructing the flow by using the porous membrane), the membrane is effective to at least partially obstruct blood flow into the aneurysm; and permit blood flow through pores in the membrane and into that blood supply to perforators and/or microscopic branches of brain arteries.

With respect to the statements of what the membrane is effective to do (capable of), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Additionally, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Dereume teaches all the claimed limitations discussed above however, Dereume does not disclose that the membrane has a substantially uniform porosity.

Fierens discloses a mechanically expandable device (32) with a membrane (38) that contains a substantially uniform porosity (last sentence of [0024] and [0087]) along its length (Fig. 11 and [0087] last line).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Dereume with a uniform porosity in view of the

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teachings of Fierens, in order to promote cell in growth as well as reducing the risk of embolic release through out the length of the device equally.

Claims 39 and 75: Dereume discloses that the membrane expands in response to expansion of the first mechanically expandable device (Fig. 9-13).

Claims 40 and 76: Dereume discloses the method wherein the membrane expands in response to expansion of the first and second mechanically expandable devices (Fig. 9-13).

12. Claims 32, 33, 70, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudakov et al (6,451,050) in view of Fierens et al. (2002/0035394) and further in view of Dereume et al. (5,639,278).

Claims 32 and 70:

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that at least one radiopaque marker is made from gold or platinum.

Dereume discloses that at least one radiopaque marker is made from gold or platinum (Col. 14 Lines 44-46).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with a radiopaque marker made of gold or platinum in view of the teachings of Dereume, since this materials are well known in the art to be used as radiopaque markers.

Claims 33 and 71:

Rudakov discloses that there is a radiopaque marker at the end of the expandable device (Col. 4 Lines 17-19).

Rudakov in view of Fierens teaches all the claimed limitations discussed above however, Rudakov in view of Fierens does not disclose that there is radiopaque marker at the center of the expandable device.

Dereume discloses that there is radiopaque marker at the center of the expandable device (Col. 14 Lines 38-44). The radiopaque marker is placed in the bifurcation area which is at the center of the mechanical expandable device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Rudakov in view of Fierens with a radiopaque marker at the center of the device in view of the teachings of Dereume, in order to provide visualization of the graft and specifically of the area where the bifurcation or aneurysm is located.

### ***Response to Arguments***

13. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the 112 rejections described above.

As stated in the 112 rejections, the claimed invention has enabling and written description issues which bring up issues that make the claims indefinite to the examiner. Specifically, the examiner is still not clear how the uniform porosity membrane does not allow blood flow through one portion of the device but not through the other in view of the original disclosure.

In view of the 112 rejections, the prior art rejection was maintained.

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14. With respect to applicant's arguments of the 112 indefinite rejection, the applicant asserts that is well known in the art that blood flow between vascular region through a porous membrane is dependent in several factors (page 15 last paragraph of applicant's arguments), however applicant does not show any support for the statement.

In addition, it is noted that the features upon which applicant relies (i.e., membrane thickness, size, spacing, and density of the pores) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regards to the factor of the size and spacing of the pores, it would not be applicable in the claimed invention since it is claimed that the porosity if uniform therefore the size and spacing of the pores are the same throughout the membrane.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773